UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,159	02/05/2002	Bernard Bihain	29.US4.DIV	2627

23557 7590 12/27/2004

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
HUNNICUTT, RACHEL KAPUST	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,159	BIHAIN ET AL.	
	Examiner	Art Unit	
	Rachel K. Hunnicutt	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-85* is/are pending in the application.

4a) Of the above claim(s) *73 and 76-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72,74 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/485,316.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0404 and 1004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 72 and 74-77) with traverse in the response dated October 18, 2004 and election of obesity-related type II diabetes and ApM1 is acknowledged. Applicants submit that pending claims 72 and 74-75 read upon the elected invention. Applicants' comments regarding subsection (a) of the election of species are noted. The partitioning of dietary lipids, the reduction of levels of free fatty acids, and the decrease in body weight are all effects of administering the same compound—they are not different methods of treatment. Thus, the requirement for an election of species among subsection (a) is withdrawn. Claims 72-85 are pending in this application. Claims 73 and 76-85 are withdrawn from consideration as being drawn to non-elected inventions and/or non-elected species. Claims 72 and 74-75 are under examination as they pertain to the elected species of treating obesity-related type II diabetes and ApM1.

Priority

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

It is noted that Applicants state the current application is a divisonal of U.S. Application No. 09/485,316, however the status of 09/485,316 is not included. Applicants need to amend the specification to indicate that 09/485,316 has issued into patent no. 6,344,441.

Specification

The use of the trademarks SUPERSCRIPT™ (p. 25) and MATCHMAKER™ (p. 42) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 72, 74, and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 72, 74, and 75 are drawn to a method of using an agent which "influences" the partitioning of dietary lipids to treat conditions wherein it is desirable to increase the partitioning of dietary lipids. "Influences" would include both increasing partitioning and decreasing partitioning, but the claims are drawn to treating conditions in which "it is desirable to increase the partitioning of dietary lipids to the liver." Thus, it appears that only agents which increase the partitioning of dietary lipids to the liver are meant to be encompassed.

Claims 72, 74, and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 72, 74, and 75 encompass methods of treating lesions due to obesity-related Type II diabetes, wherein AdipoQ, ApM1, or Acrp30 is administered. The specification treats AdipoQ, ApM1, and Acrp30 as different proteins, however according to the art AdipoQ, ApM1, and Acrp30 are the same protein known as adiponectin (see Fasshauer *et al.* (2004), *Biochimie* 86(11): 779-784). If the AdipoQ, ApM1, and Acrp30 of the current

application are meant to be distinct proteins distinguishable from adiponectin, Applicants are requested to clarify the differences between the three proteins. Otherwise they will be treated as the same protein.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72, 74, and 75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of administering ApM1 to reduce plasma triglyceride levels or to reduce body weight, does not reasonably provide enablement for methods of administering any agent which influences the partitioning of dietary lipids between the liver and peripheral tissues, ApM1 or fragments of ApM1 to treat microangiopathic lesions, ocular lesions, or renal lesions resulting from obesity-related type II diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention; 2) state of the prior art; 3) relative skill of those in the art; 4) level of predictability in the art; 5) existence of working examples; 6) breadth of claims; 7) amount of direction or guidance by the inventor; and 8) quantity of experimentation needed to make and/or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicants teach that ApM1 can reduce plasma triglyceride levels and it can also reduce body weight. However, Applicants do not provide any examples that show ApM1, fragments of ApM1, or any agent which influences the partitioning of dietary lipids between the liver and peripheral tissues can be used in the treatment of microangiopathic lesions, ocular lesions, or renal lesions resulting from obesity-related type II diabetes. It is not possible to correlate reduced plasma triglyceride levels or reduced body weight with treating different disorders associated with type II diabetes. Bays teaches that "because studies in antiobesity research are in such a state of infancy, it is difficult to determine which of these single treatment targets, or

which combination of treatment targets, has the best potential to effectively manage the worldwide epidemic of obesity. Therefore, it is impossible to predict at this point which agent or agents will eventually prove to revolutionize obesity treatment" (Bays (2004), *Obesity Research* 12(8): 1197-1211). Fasshauer *et al.* teach that while adiponectin may be a therapeutic target for increasing insulin sensitivity and improving vascular function, various areas of uncertainty still need to be addressed to successfully transform the knowledge into clinical practice (Fasshauer *et al.* (2004), *Biochimie* 86(11): 779-784). For example, on p. 782 Fasshauer *et al.* teach that a transgenic mouse model with threefold elevated circulating adiponectin concentrations has an unexpected phenotype with interscapular and intraconal fat accumulation, the latter resulting in significant exophthalmus. On p. 782 Fasshauer *et al.* also teach that it "is far from clear which fragments and oligomeric states of adiponectin are important for its beneficial effects not only in vitro but also in vivo."

Thus, due to lack of working examples, the quantity of experimentation needed, the state of the prior art, and the level of predictability in the art, one skilled in the art would not know how to make and/or use the invention commensurate in scope with these claims.

Conclusion

NO CLAIMS ARE ALLOWED.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

Gil-Campos *et al.* (2004), *Clin. Nutr.* 23(5): 963-974

Hu *et al.* (1996), *J. Biol. Chem.* 271(18): 10697-10703

Maeda *et al.* (1996), *Biochem. Biophys. Res. Comm.* 221: 286-289

Scherer *et al.* (1995), *J. Biol. Chem.* 270(45): 26746-26749

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
12/23/04

JANET ANDRES
PRIMARY EXAMINER